

The following is a summary of the information published in the Federal Register on April 27, 2001, regarding PA 99-050, Comprehensive Community Treatment Program for the Development of New and Useful Knowledge (Short Title: Community Treatment Program)

AGENCY: Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), DHHS

ACTION: Change in eligibility and a special funding opportunity under SAMHSA/CSAT Comprehensive Community Treatment Program (PA 99-050)

CHANGE IN ELIGIBILITY: This notice is to inform the public that the eligibility requirements in the SAMHSA/CSAT program announcement: PA 99-050-Comprehensive Community Treatment Program for the Development of New and Useful Knowledge (Short Title: Community Treatment Program) will be changed immediately following the May 10, 2001 receipt date for applications. Effective May 11, 2001, for profit entities will not be eligible applicants under this program. On October 17, 2000, Public Law 106-310 reauthorized SAMHSA. Section 509 of the law authorized CSAT, through the Secretary, DHHS, to carry out activities described in the section directly or through grants or cooperative agreements with States, political subdivisions of States, Indian tribes and tribal organizations, and other public or nonprofit private entities. For profit entities are **excluded** under section 509; therefore, for profit entities are no longer eligible to apply for grants under PA 99-050. Applications received for the May 10, 2001, or earlier receipt dates, are not affected by this change.

PA 99-050, Community Treatment Program, was published in the *Federal Register* on March 8, 1999 (Vol. 64, Number 44, pages 11027-11031). A modification/clarification notice for PA 99-050 was published in the *Federal Register* on December 13, 1999 (Vol. 64, Number 238, pages 69544-69545).

SPECIAL FUNDING OPPORTUNITY: Subject to the availability of funds, an additional \$500,000 will be allocated to PA 99-050, Community Treatment Program, to support exploratory/pilot studies related to managed care. Pilot studies may be submitted that are responsive to the following areas: (1) evaluation of substance abuse treatment computerized clinical and/or patient decision support systems and/or (2) examining the links between established substance abuse performance measures, e.g., Washington Circle Group Performance Measures and Treatment Outcomes. Exploratory/pilot study proposals should build upon the existing resources within substance abuse treatment delivery systems. This notice applies to applications submitted for the September 10, 2001 receipt date only. It is anticipated that 4-5 grants will be awarded.

Applicants must follow the eligibility criteria (except, as noted above, for profit entities are not eligible) and guidelines for preparing and submitting an application presented in the complete program announcement (PA 99-050). The complete announcement and application materials and the December 13, 1999 addendum that includes modified/clarified sections are available through the SAMHSA web

site—www.samhsa.gov or from the National Clearinghouse for Alcohol and Drug Information (telephone 800-729-6686).

Additional information related to exploratory/pilot studies related to managed care may be obtained from:

Sarah Wattenberg
Office of Managed Care
Center for Substance Abuse Treatment, SAMHSA
Tele: 301-443-0092

General questions related to program announcement PA 99-050 should be directed to:

Tom Edwards, Jr.
Division of Practice and Systems Development
Center for Substance Abuse Treatment, SAMHSA
Tele: 301-443-8453

Note: Potential applicants under this SAMHSA/CSAT initiative should be aware that this program could be updated and reannounced in the *Federal Register* within the next year.

ADDENDUM to PA 99-050
Published in the Federal Register December 13, 1999

ADDENDUM to SAMHSA/CSAT Program Announcement PA 99-050, Comprehensive Community Treatment Program for the Development of New and Useful Knowledge.

The following changes to the appended PA 99-050 modify/clarify the Purpose and Rationale, Eligibility, Availability of Funds, Period of Support, and Program Description and Project Requirements sections. It is important to note that potential applicants for the May 10, 2000 and future receipt dates must take the following modifications/clarifications into consideration before preparing and/or submitting an application.

PURPOSE AND RATIONALE

(Replace the existing second sentence of the third paragraph with the following.)

Through this Program Announcement (PA), CSAT will support two types of grants: 1) full studies of treatment programs and services, and 2) exploratory/pilot studies.

Note: CSAT will no longer support enhancement/expansion grants under this PA; therefore, all references to enhancement/expansion grants throughout the PA should be ignored.

ELIGIBILITY

(The second paragraph of the Eligibility section has been deleted.)

Note: The enhancement/expansion grant category will not be funded.

AVAILABILITY OF FUNDS

(Replace the existing Availability of Funds section with the following.)

It is estimated that \$2.5 million will be available to support awards under this PA in FY 2000. The amount of an award is expected to range as follows (amounts include direct and indirect costs):

Full studies: up to \$500,000;

Exploratory/Pilot studies: up to \$250,000;

Funds will be divided between the two grant categories. The number of applications funded in each category will depend on the quality of applications as determined by the peer review process. Funds may be used to conduct all aspects of data collection and evaluation. Limited funds are available to support substance abuse treatment intervention services and substance abuse related services necessary

for successful conduct of the proposed study. Applicants are strongly encouraged to verify future receipt dates and availability and terms of funding before preparing and submitting applications (see Application Receipt and Review Schedule).

PERIOD OF SUPPORT

(Replace the existing Period of Support section with the following.)

Support for full studies and for exploratory/pilot studies may be requested for up to 3 years. Annual awards will be made subject to continued availability of funds and progress achieved.

SECTION II - PROGRAM DESCRIPTION AND PROJECT REQUIREMENTS, B. PROGRAM PLAN, 3) ENHANCEMENT/EXPANSION GRANTS

(Section 3- Enhancement/Expansion Grants has been deleted.)

Note: The enhancement/expansion grant category will not be funded.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

**SUBSTANCE ABUSE AND MENTAL HEALTH
SERVICES ADMINISTRATION**

CENTER FOR SUBSTANCE ABUSE TREATMENT

**COMPREHENSIVE COMMUNITY TREATMENT PROGRAM FOR
THE DEVELOPMENT OF NEW AND USEFUL KNOWLEDGE**

SHORT TITLE: COMMUNITY TREATMENT PROGRAM

**Program Announcement (PA) No. PA 99-050
Part I - Programmatic Guidance**

Catalog of Federal Domestic Assistance (CFDA) No. 93.230

Under the authority of Section 501(d)(5) of the Public Health Service Act, as amended (42 USC 290aa), and subject to the availability of funds, the SAMHSA Center for Substance Abuse Treatment will accept applications in response to this Program Announcement for the initial receipt date of May 10, 1999.

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Date of Issuance: March, 1999

Part I - PROGRAMMATIC GUIDANCE
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[Note to Applicants: In order to prepare an application, PART II, "General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements" (February 1999 edition), must be used in conjunction with this document, PART I, "Programmatic Guidance."]

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SECTION I. OVERVIEW

Purpose and Rationale

The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) announces the availability of grants to support the development or modification of treatment approaches for special populations and/or service settings and to support rigorous study of their effectiveness.

The purpose of this program is to generate new knowledge about three aspects of substance abuse treatment: 1) special populations, 2) integrated substance abuse treatment, screening, and early intervention in non-traditional settings, and 3) innovative programs.

This grant program, hereinafter referred to as "Community Treatment Program," is a vehicle by which treatment providers and other experts in the substance abuse treatment field can identify innovative clinical and service delivery approaches in need of development and study. Through this Program Announcement (PA), CSAT will support three types of grants: 1) full studies of treatment programs and services, 2) exploratory/pilot studies; and 3) enhancement/expansion grants. Applicants must clearly indicate which type of grant they are applying for in their application to SAMHSA. Lastly, CSAT seeks to promote partnerships and collaboration between community-based organizations, to foster broad participation among researchers, practitioners, consumers, and payers, and to support the development of an infrastructure to facilitate knowledge development (see Section IV).

Eligibility

Applications for full studies of treatment programs and services and exploratory/pilot studies may be submitted by public and domestic private nonprofit and for-profit entities, such as units of State or local government, community-based organizations and State or private universities, colleges, and hospitals.

Applications for enhancement/expansion grants may be submitted by currently active CSAT grantees (including those in no cost extension periods) who can demonstrate successful

implementation of planned activities in their current project. These grants are restricted to currently active grantees because their studies are in place allowing them to immediately proceed to the next step of expanding the project's scope to improve the knowledge base. In addition, because their study structure, database, enrolled participants, relationships with participants and their families, and collaborating organizations are already established, start-up time for the enhancement/expansion is minimal.

Availability of Funds

It is estimated that \$5.3 million will be available to support approximately 15 awards under this PA in FY 1999. The amount of an award is expected to range from \$100,000 to \$500,000 in total costs (direct + indirect). Only with a clear and strong justification will awards in excess of \$500,000 be considered. Funds will be divided evenly among the three types of grants. The number of applications funded in each group will depend on the quality of applications as determined by peer review. Funds may be used to conduct all aspects of data collection and evaluation. Limited funds are available to support substance abuse treatment intervention services and substance abuse related services necessary for successful conduct of the proposed study. Applicants are strongly encouraged to verify future receipt dates, and availability and terms of funding before preparing and submitting applications (see Application Receipt and Review Schedule).

Period of Support

Support may be requested for a period of up to 3 years. Annual awards will be made subject to continued availability of funds and progress achieved.

Section II. PROGRAM DESCRIPTION & PROJECT REQUIREMENTS

A. Statement of the Issue

Past Knowledge Development and Application (KD&A) activities, as well as research from NIDA, NIAAA, and NIMH (in the case of co-morbidity), point to a need to develop and/or modify treatment approaches for special populations, service settings outside of the traditional substance abuse treatment sites,

and integration and coordination of comprehensive services to identify and respond to the numerous and interacting needs of clients in treatment. The substance abuse treatment field, and service consumers and their families, require continuing focus on the development and study of innovative clinical and service delivery approaches that will result in more effective and efficient substance abuse treatment practice.

Delivery of substance abuse treatment services, as well as other human services, is complicated by rapidly changing demographics of the persons needing and receiving services and of the communities in which the services are provided and received. These changes include the implementation of managed care. Service providers have shown great ingenuity and creativity in modifying their service delivery approaches to meet the challenges presented by these changes. Examples of these results are seen in specialized service units, ethnically and gender-diversified staff, increased scope and continuity of staff training, identification of persons in need of treatment, varied approaches to outreach and recruitment as well as development of new organizational forms to provide treatment.

Despite the above, the demand for more effective and innovative substance abuse treatment programs and approaches/models designed for both non-traditional and standard treatment settings continues. Also, there remain special populations whose needs have not been well defined and addressed, and whose requirements in accessing and continuing with treatment are not yet known or well understood.

As mentioned in Section I. Overview, CSAT wishes to examine three areas related to treatment of addicted persons: 1) special populations, 2) integrating substance abuse treatment, screening, and early intervention in non-traditional settings, and 3) innovative programs. A justification of these areas is provided below. The applicant can submit an application that addresses any or a combination of these areas (e.g., innovative programs that capitalize on the integration of substance abuse treatment in the school setting or a primary health care site). A limited list of references is provided in Appendix A.- Bibliography. Terms used in this announcement are defined in Appendix B.-Definitions.

1) Special Populations

Changing demographics in the general population and among addicted persons have prompted service providers and policy makers to modify traditional addiction treatment approaches in an attempt to meet the needs of people from special populations. By their nature, the populations of interest here are "special" because their problems are not well understood or defined, the problems resist resolution, the people themselves are difficult to contact, they do not remain in treatment, their treatment effects are short-lived, or providers are struggling to identify an effective treatment model for them. The characteristics of "mainstream" programs may limit the program's ability to recruit or maintain these populations. Proposed treatment approaches for special populations are expected to identify the unique needs of the population members and develop and test effective strategies for recruiting, assessing, motivating, providing treatment, retaining appropriate contact, and involvement of members of special populations.

2) Integrating Substance Abuse Treatment, Screening, and Early Intervention into Non-Traditional Settings

Substance abuse treatment services have traditionally been provided in four treatment settings: inpatient hospitals, residential treatment facilities, intensive outpatient programs, and outpatient settings. Research provides strong evidence that addicted clients experience significant, meaningful, and positive changes in biopsychosocial functioning following addiction treatment in all of these treatment settings (SAMHSA, 1998). However, CSAT wishes to study the effectiveness and efficiency of providing substance abuse treatment in non-traditional settings that are easily accessible to people and that are part of their current environment. Examples of these are the workplace, schools, and primary health care sites.

Many changes are having a profound impact on the health care system, including drug treatment. Managed care continues to move rapidly into public alcohol and drug addiction treatment service delivery and financing. Many substance abuse treatment administrators are using some form of managed care for publicly funded behavioral health services in an effort to control costs and reduce inefficiency.

Over 70 percent of the substance abusing population is employed (SAMHSA, 1998). Employee Assistance Programs (EAPs) are providing drug treatment, needs identification, referrals, interventions, and follow-up, as well as serving as gatekeepers for managed care organizations. Innovative approaches need to be developed to address the needs of distinct substance abusing populations in EAPs and workplace settings.

Primary care settings and schools have rarely been systematically developed as resources for substance abuse problem identification/diagnosis, or treatment; nor do these entities often function as part of a coordinated substance abuse treatment services delivery system. Issues of eligibility, funding, training, and the approaches and policies peculiar to primary health care are neither well formulated nor adequately addressed.

3. Innovative Programs

Innovative substance abuse treatment programs involve new approaches to deal with difficult issues. Innovative programs to be developed and evaluated need to address issues such as: co-morbidity with mental illness, HIV/AIDS and/or other serious medical needs, rural health, physician office-based opioid treatment (OBOT), physician office-based treatment of other substance abuse problems, clients with criminal justice involvement, clients with disabilities, community outreach, and home health treatment. In addition, the significant impact of managed care on these types of innovative programs cannot be ignored.

Addiction, treatment, and sustained recovery are dynamic and present multi-faceted challenges. No single program or strategy will be effective for all people who seek treatment. Rather, clients who have distinctive treatment needs will experience greater or less treatment success through different delivery programs at different stages of the addiction process. Difference in treatment success generally relates to the ability of the program to recognize and address distinct treatment needs. This suggests that programs should aggressively promote the concept of a continuum of care and provide easy access to a variety of treatment approaches and services through inter-program alliances, networks, and case management. It is anticipated that the more comprehensive the

treatment, the more treatment needs will be met, and the more successful treatment outcomes should be.

The grantee's expected contribution to the field for these three aspects of substance abuse is the production of information in the form of outcome data, treatment manuals, training programs, publications and presentations that will advance the field's ability to provide effective, efficient substance abuse treatment.

B. Program Plan

Several types of studies are allowed under this PA. As mentioned in Section I. Overview, CSAT will support three types of grants. A description of these grants is provided below.

1) Full Studies of Treatment Programs and Services

Full studies of treatment programs and services are studies that assess clinical effectiveness and associated costs of treatment programs and services. These studies will typically compare process and outcomes of at least one innovative intervention compared to those for one or more comparison or control conditions. True experimental, random assignment designs are preferred. Quasi-experimental designs are acceptable when experimental designs are not practical. These studies should assess main effects associated with differences between interventions, and should examine other effects such as those associated with client characteristics, dosage, length of stay, and managed care, including issues related to financing.

Grant funds may be used for support of data collection and evaluation; limited funds are available for enhancement or modification of services necessary to ensure adequate client flow to test proposed hypotheses.

2) Exploratory/Pilot Studies

CSAT will support exploratory or pilot studies of the feasibility or development of methodology, participant recruitment/assignment procedures, instrumentation, and treatment protocols including methodologies for studying managed care. It will also support studies that examine

preliminary intervention effects. Such studies should be designed to contribute significantly to the development of larger, more definitive studies.

3) Enhancement/Expansion Grants

The purpose of enhancement/expansion grants is to improve the knowledge base and contribute to the original purpose of a current CSAT-funded grant through activities such as: adding additional participants to increase sample size or diversity; longer follow-up; additional data collection and analysis; or development of additional products (e.g., treatment manuals, training packages, publications, conference presentations, workshops, etc.).

Applications may be submitted by currently active CSAT grantees in single-site studies, multi-site studies (including coordinating centers), and cooperative agreement programs. Each currently active grantee must submit a separate application. CSAT will award enhancement/expansion grants only to enable currently active grantees that can demonstrate successful implementation of planned activities during the original period of grant award (including no cost extension periods) to implement a significant expansion in the project's scope or study protocol. These grants may not be used to allow currently active grantees to implement activities or fulfill requirements scheduled for the original period of grant award.

Potential Study Topics

Treatment providers and other experts in the treatment field are encouraged to identify clinical and service delivery approaches in need of development and study that: are culturally responsive, appropriate, and sensitive; improve the identification of clinical treatment needs and address those needs; determine the best approaches for outreach, engagement, and retention of hard to reach populations; and identify and describe state of the art and science treatment modalities.

CSAT has a substantial interest in funding projects that address, e.g., any one or more of the following concerns:

1. Studies of innovative clinical practices and management techniques that provide treatment services at reasonable costs in relation to outcomes.

2. Outreach studies to assess strategies to expand treatment services to under-served populations and geographic areas, such as rural communities and inner cities.
3. Studies on the impact of innovative practices directed at consumer choice, treatment program selection, and treatment retention. The characteristics of treatment completers and treatment dropouts should be studied to determine their differences and possible ways in which treatment dropouts may be induced to remain in treatment. The decision-making process leading to reasons to leave treatment, including the roles of drug-related neuro-psychological deficits, family members, and coercion in deciding to seek treatment, requires study.
4. The effects of various organization and financing strategies such as managed care on access to and the costs, quality, and outcomes of care for high-risk drug abusers (e.g., effects of private insurance coverage, Medicaid waivers, block grants, fixed budgets, multiple funding sources, and various costs and utilization controls as a part of financing programs, as in managed care).
5. Barriers to service access and utilization for specific high-risk populations, such as HIV-positive clients and physically or cognitively disabled clients, and the effectiveness of alternative strategies for overcoming these barriers.
6. Service system models to improve the quality and effectiveness of drug abuse treatment services, including matching, referral, and other linkage processes.
7. Improvement of linkages and liaisons with external resources, including improvements in the management of information and access to service networks.
8. Studies of the role and effectiveness of other supportive services (e.g., outreach, transportation, child care, psychological services, housing, nutrition and diet, vocational programs, family assistance, and legal services) on client outcome in linkage programs or programs providing brief interventions, especially for special populations.

9. Studies on the substance abuse treatment effects of Employee Assistance Programs on workplace productivity and on treatment outcome. Other studies of the EAPs include those related to the effects of gatekeeper roles for managed care on access to treatment.

10. The implementation and outcome of school-based substance abuse screening and referral, and/or treatment.

11. The role of the primary care provider in diagnosing substance abuse problems and providing a substance abuse treatment plan.

11. Studies whose objectives are to find chronic, hardcore drug users and their sex and/or needle-sharing partner(s) in order to: 1) encourage and facilitate entry into substance abuse treatment; 2) provide medical diagnostic services for HIV, hepatitis B and C, STDs, and TB; and 3) provide the information, skills, and other prophylactic means to effect those behavior changes most likely to decrease the risks of acquiring or transmitting HIV and related diseases.

Applicants may also propose studies that are concerned with other substance abuse issues.

C. Design, Methodology, Data Collection, and Analyses

No single design or approach will suit all situations. A range of study methods may be proposed, as appropriate to settings and study questions.

Requirements for Applicants

All Applicants: There are minimum expectations for all studies conducted through this PA, and all applications should address the issues that follow. All applicants should describe their study design and the procedures to accomplish the specific goals of the proposal, discuss potential difficulties and limitations of the proposed design and procedures, and discuss data collection, analysis, and interpretation.

Exploratory/Pilot Study Applicants: Method and design

requirements for exploratory/pilot studies may differ from those for full-scale studies. Depending on study goals, sample sizes may be small, comparison groups may be unnecessary, process but not outcome may be the focus, etc. Therefore, applicants for exploratory/pilot study grants should address all applicable headings in this section and state when specific provisions are not applicable.

Enhancement/Expansion Grant Applicants: Applicants for enhancement/expansion grants should describe design and method procedures currently in use and those proposed for enhancement/expansion. Each applicant should present its specific design and method and describe how those relate to the current study.

Coordinating Centers of multi-site studies applying for enhancement/expansion grants should present an overview of the study, including findings to date, describe the coordinating center role in the current study and in the proposed enhancement/expansion, and describe plans for collecting, managing, and analyzing multi-site data.

Purpose

Applicants must specify the purpose of the proposed study, the questions or hypotheses to be tested, and (as applicable) the anticipated program, system, and client outcomes. Applicants must also define the target population.

Theoretical Framework

Applicants must describe the guiding theoretical framework for their proposed intervention. Applicants should present a logic model that depicts why the intervention will produce expected results.

Design

CSAT anticipates that most applications funded through this PA will address client outcomes. Applicants must describe a study design that will enable determination of outcomes attributable to the proposed intervention(s) and why the design was selected. Applicants should propose and justify the best possible design that is consistent with the goals of their proposed study. They must also describe the weaknesses

of the proposed design and how the weaknesses will be minimized. If an experimental design with random assignment is proposed, the applicant must discuss the practical considerations of such a design, and document the applicant's capability of conducting a random assignment study.

Applicants proposing random assignment designs must include agreement from participating service providers to permit randomization. For other design options, the applicant must discuss the reason for selecting a non-experimental design, and how non-equivalence will be assessed and managed. For all proposed designs, ethical issues must be addressed. Designs that assign participants to "no treatment" conditions are not acceptable. Assignment to delayed treatment control or comparison groups may be proposed if appropriate safeguards to clients are employed and specified in the application.

Methodology

Applicants must address the following:

Control or Comparison Group(s): Describe the essential characteristics of the comparison target population, program structure, and program intervention. Discuss the critical differences in treatment between the control or comparison group(s) and the targeted intervention. Present reasons why client outcomes for the targeted intervention are expected to be different from those of the comparison group(s).

Study Sample: Define the proposed sample size. State and provide a rationale for inclusion/exclusion criteria. Describe the degree to which the study population reflects the cultural, racial/ethnic, language, and gender issues of the community. Provide a justified estimation of the response rates, how many clients will be recruited into the evaluation study, and how many are likely to be retained. Explain recruitment and retention procedures, including an incentive plan, if any. Document how attrition problems will be handled when and if they arise, while maintaining an adequate sample size. Provide assurances that the needed sample sizes will be available to conduct the study within the time allocated for intervention and control/comparison groups.

Power Analyses: Employ power analyses for major hypotheses. Present justification for effect sizes used to calculate the

power analyses and discuss program's capability of achieving the required sample size. [Power analyses may not be appropriate for some exploratory/pilot studies focusing on feasibility of methods, interventions, or designs.]

Data Collection and Analyses

Applicants must address the following:

Data Points: Collect client data at baseline or intake, treatment completion, and follow-up post treatment; additional data points may be proposed.

Instruments: Describe and provide rationale for the specific evaluation measures, both independent and dependent, to be used and data to be collected to address the evaluation questions. Discuss the appropriateness and psychometric properties of the instruments that will be used to measure program and client variables for the population being assessed (e.g., reliability, validity, appropriately normed, used for this population in other research, standard measure for this purpose). Attend particularly to age, gender, and culture appropriateness. Describe plans to obtain verification of self-reported substance abuse through biological analysis and/or other informants.

Sources: Identify specific sources for collection of data (e.g., client records, patients/clients), and the method of data collection for each source (e.g., in-person interviews, telephone interviews, records review). Describe the data collection plan (specify when and by whom data will be collected with each instrument) from each data source. Discuss how data collection will be sensitive to age, ethnic, cultural, language, and gender considerations.

Qualitative Data: Present plans for obtaining qualitative information relevant to the evaluation, and how such information will be used.

Analysis Plan: Describe the relationship between quantitative and qualitative data, major study questions, and analytic techniques to be employed.

Reporting and Utilization Plan: Describe how and when outcome evaluation findings – including preliminary results – will be reported and the anticipated use of the findings.

Systems Change: Applicants proposing interventions with expected impacts on systems must define the target system, the measures to be used to assess the system, at what time points measures will be applied, and how data will be used to describe the system and to assess systems change.

Cultural Competence: CSAT expects both interventions and evaluations to be culturally competent. Applicants must show how cultural competency of services and evaluations will be defined, ensured, and assessed.

Performance Monitoring (GPRA)

Applicants must demonstrate how the evaluation will demonstrate effectiveness of proposed interventions in achieving CSAT's Government Performance and Results Act (GPRA) standard outcome requirements. Applicants must clearly state when, because of the target population to be served or the type of services to be provided, one or more goals are inappropriate and will not be addressed. CSAT's GPRA Strategy is described in Appendix C.

CSAT's GPRA measures are:

- # Adults: Percent of service recipients employed, permanently housed in community; with no/reduced involvement with criminal justice system, with no/reduced alcohol or illegal drug consequences; and with no past month substance abuse.
- # Adolescents in Treatment: Percent of adolescents who are service recipients, who are attending school, in stable living environments, have no/reduced involvement in juvenile justice system, have no past month use of alcohol or illegal drugs, and have no/reduced alcohol or illegal drug consequences.

D. Project Management: Implementation Plan, Organization, Staff, Equipment/Facilities, Budget, and Other Support

Applicants must provide the following information in the application.

Implementation Plan: Provide a plan for implementing the study

that includes tasks, time lines, and responsibilities.

Implementation Fidelity: Describe the plan to evaluate the processes of implementation and the adherence of interventions and procedures to those proposed. Applicants should discuss evaluation of processes and services within control/comparison groups as well as those within the experimental/intervention groups.

Organization: Discuss the capability and experience of the organization in dealing with similar projects and populations. Discuss the extent to which the organization has or plans to collaborate with other service agencies, institutes, non-profits, Tribal Councils, National Tribal organizations, universities, clinics, or organizations.

(Note: For enhancement/expansion grants, in addition to the above, discuss extent of collaboration with evaluators and academicians.)

Staff: Provide evidence that the proposed staffing is appropriate and adequate for implementation of the project. Describe the qualifications of the project director, study coordinator, and other key personnel including proposed consultants and subcontractors. Describe the extent to which the staff is reflective of the target population or demonstrate cultural competence to ensure sensitivity to language, age, gender, race/ethnicity, sexual orientation, and other cultural factors related to the targeted population.

Applicants must provide an Organizational Structure/Timeline/Staffing Patterns chart as Appendix 1.

Equipment/Facilities: Discuss the availability and adequacy of resources and equipment. Document that the services provided in a location/facility are adequate and accessible and the environment is conducive to the population to be served.

Budget: Provide a detailed reasonable budget including all identified potential expenses required to achieve successful completion of the project plan and management.

Other Support: Describe the adequacy of additional resources not budgeted for that will be utilized to implement this project, if applicable. Discuss the appropriateness of a plan to secure resources in order to phaseout or extend this

project beyond the federal funded program years, if applicable.

Section III. GUIDELINES AND REVIEW CRITERIA FOR APPLICANT

Guidelines

Applications submitted in response to this PA will be reviewed for scientific/technical merit in accordance with established PHS/SAMHSA review procedures outlined in the Review Process section of Part II. Applicants must review the Special Considerations/Requirements and Application Procedures sections that follow, as well as the guidance provided in Part II, before completing the application.

It is important to note that review criteria A-D below correspond to subsections A-D in the prior Program Description section to assist in the application process. The response to each review criterion and each bulleted statement under each criterion should be from the perspective or role of the applicant. Applicants must follow the review criteria headings and bulleted statements for the format/structure of the Program Narrative portion of the application.

Applications will be reviewed and evaluated according to the review criteria that follow. The points noted for each criterion indicate the maximum number of points the reviewers may assign to that criterion if the application is considered to have sufficient merit for scoring. The assigned points will be used to calculate a raw score that will be converted to the official priority score.

The bulleted statements that follow each review criterion serve as a guide for the area(s) applicants must address under each review criterion. These statements do not have weights.

Peer reviewers will be instructed to review and evaluate each relevant criterion in relation to cultural competence. Points will be deducted from applications that do not adequately address the cultural aspects of the criteria. (See Appendix D in Part II, for guidelines that will be used to assess cultural competence.)

Review Criteria

The review criteria apply to each type of grant, except where noted.

A. Statement of the Issue (20 Points)

- # Extent to which the substance abuse problem is understood, including supportive data.
- # Extent to which the applicant's literature review demonstrates an understanding of the state-of-the-art and/or science related to the defined problem and proposed solution. (NOTE: The literature review must reflect current state of knowledge regarding culturally competent services in this area and appropriate discussion that demonstrates how the reference citations relate to the population to be served.)
- # Extent to which this project can be linked to prior related projects; yet, be innovative or necessary.
- # Extent to which the applicant demonstrates an understanding of the goals and objectives of the program as defined in this PA.
- # Extent to which the proposed project moves to resolution or resolves the stated problem, including an understanding of particular substance abuse issues related to the target population.

B. Program Plan (25 Points)

- # Extent to which applicant demonstrates an "adequate participatory planning process" which involves individuals reflective of the target population in the preparation of the application, planned implementation of the project, and data interpretations.
- # Extent to which the program plan is inclusive of and appropriately addresses age, race/ethnic, cultural, language, sexual orientation, gender, and disability issues in the proposed activities such as models, outreach, intervention, and/or services.
- # Extent to which HIV/AIDS will be addressed in the proposed project, when applicable.

NOTE: For enhancement/expansion grants, demonstration of successful implementation of planned activities during the initial period of grant award.

C. Design, Methodology, Data Collection, & Analyses (30 Points)

Design

- # Extent to which the proposed study design addresses the program's and proposed project's plans and goals, including cultural appropriateness.
- # Adequacy of the rationale provided when secondary study questions are proposed.

Methodology

- # Extent to which the applicant demonstrates that the methodology is conducive to design and study question(s), as well as appropriate for the target population.
- # Extent to which the applicant demonstrates the ability to identify, recruit, and retain the target population at the study site(s), or for the intended services.
- # Appropriateness of the analytic design, including power analyses for adequate sampling, and strategies to control for bias and confounding variables, or the evaluation of services process.
- # Extent to which applicant has strategies for documenting the project for purposes of future replication and product/ knowledge dissemination.
- # Extent to which the proposed project can supply the necessary agency GPRA data for information on adherence to intervention design, validity of results, dissemination of findings and next steps.
- # Appropriateness of the proposed project's post-execution evaluation plan to monitor the performance of the project.

Data Collection and Analyses

- # Appropriateness of measurement selection or evaluation instrument; that is, validity and reliability of existing measures selected or strategies for obtaining validity and

reliability of measures to be developed, and the appropriateness of the aforementioned measures for the target population.

- # Appropriateness of strategies for data management, data processing and clean-up, quality control, and data retention.
- # Extent to which GPRA client outcomes can be collected, if applicable.
- # Appropriateness of analytic and statistical strategies to provide reliable and valid findings.
- # Extent to which target population is involved in the interpretation of the findings.

D. Project Management: Implementation Plan, Organization, Staff, Equipment/Facilities, Budget, and Other Support (25 Points)

Implementation Plan and Fidelity

- # Extent to which the proposed plan implements the design and is timely, feasible, achievable, and realistic, as well as culturally appropriate.
- # Appropriateness of plan to evaluate the processes of implementation and the adherence of interventions and procedures to those proposed.

Organization

- # Capability and experience of the applicant organization with similar projects and populations.
- # Extent to which there is collaboration with other service agencies, institutes, non-profits, Tribal Councils, National Tribal Organizations, universities, clinics, or organizations.

(NOTE: For enhancement/expansion grants, in addition to the above, extent of collaboration with evaluators and academicians.)

Staff

- # Evidence that the proposed staffing pattern is appropriate and adequate for implementation of the project.
- # Qualifications and experience of the project director, study coordinator, and other key personnel, including proposed consultants and subcontractors.
- # Extent to which the staff is reflective of the target population or can demonstrate cultural competence to ensure sensitivity to language, age, gender, race/ethnicity, sexual orientation, physical or cognitive disability, and other cultural factors related to the target population.

Equipment/Facilities

- # Adequacy and availability of resources and equipment.
- # Evidence that the activities or services are provided in a location/facility that is adequate and accessible, and the environment is conducive to the population to be served.

Budget

- # Reasonableness of the overall budget required to achieve successful completion of the project design and management.

Other Support

- # Adequacy of additional resources not budgeted for that will be utilized to implement this project, if applicable.
- # Appropriateness of a plan to secure resources in order to phaseout or extend this project beyond the federal funded program years, if applicable.

Section IV. SPECIAL CONSIDERATIONS/REQUIREMENTS

SAMHSA's policies and special considerations/requirements related to this program include:

- # Population Inclusion Requirement

- # Government Performance Monitoring
- # Healthy People 2000 (The Healthy People 2000 priority areas related to this program are: alcohol and other drugs.)
- # Consumer Bill of Rights and Responsibilities
- # Promoting Nonuse of Tobacco
- # Supplantation of Existing Funds (put documentation in Appendix 2)
- # Letter of Intent
- # Coordination with Other Federal/Non-Federal Programs (put documentation in Appendix 3)
- # Single State Agency Coordination (put documentation in Appendix 4)
- # Intergovernmental Review (E.O. 12372)
- # Confidentiality/Human Subject Protection (The SAMHSA Center for Substance Abuse Treatment Director has determined that projects funded under this program must meet Human Subject requirements.)

Specific guidance and requirements for the application related to these policies and special considerations/requirements can be found in Part II in the section by the same name.

As a result of issues identified in the Institute of Medicine (IOM, 1998) study, "Bridging the Gap Between Practice and Research," funded by SAMHSA/CSAT and NIDA, SAMHSA/CSAT, in its award decision making process will give special consideration to applicants that involve one or more of the following: (a) support partnerships and collaboration between community-based organizations/treatment programs and researchers in the development of the knowledge development initiatives from conceptualization, through development, implementation, evaluation, and interpretation of results; (b) foster broad participation among researchers, practitioners, consumers, and payers in a treatment knowledge development agenda, including measures for outcomes and program operations; and (c) support the development of an infrastructure to facilitate knowledge development within a network of community-based treatment programs and researchers. Documentation verifying one or more of these initiatives may be provided in Appendix 5 entitled, "Documentation Verifying Partnership/Collaboration/Infrastructure."

Section V. APPLICATION PROCEDURES

All applicants must use application form PHS 5161-1 (Rev. 5/96), which contains Standard Form 424 (face page). One of the following must be typed in Item Number 10 on the face page of the application form:

**PA 99-050 Community Treatment Program-FS
(if applying for full study)**

**PA 99-050 Community Treatment Program-EP
(if applying for exploratory/pilot study)**

**PA 99-050 Community Treatment Program-E
(if applying for enhancement/expansion grant)**

For more specific information on where to obtain application materials and guidelines, see the Application Procedures section in Part II.

Complete application kits for this program may be obtained from the National Clearinghouse for Alcohol and Drug Information (NCADI), phone number: 800-729-6686. The address for NCADI is provided in Part II.

Completed applications must be sent to the following address:

SAMHSA Programs
Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC-7710
Bethesda, MD 20892-7710*

*Applicants who wish to use express mail or courier service should change the zip code to 20817

APPLICATION RECEIPT AND REVIEW SCHEDULE

The schedule for receipt and review of applications under this PA is as follows:

<u>Receipt Date</u>	<u>IRG Review</u>	<u>Council Review</u>	<u>Earliest Start Date</u>
May 10, 1999	July 1999	Sept. 1999	Sept. 1999

Thereafter, applications will be received and reviewed three times per year according to the following schedule:

<u>Receipt Date</u>	<u>IRG Review</u>	<u>Council Review</u>	<u>Earliest Start Date</u>
Sept.10	Jan./Feb.	May	July 1
Jan. 10	May/June	Sept.	Dec. 1
May 10	Sept./Oct.	Jan./Feb.	Mar. 1

Applications must be received by the above receipt dates to be accepted for review. An application received after the deadline may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier and the proof-of-mailing date is not later than one week prior to the deadline date. Private metered postmarks are not acceptable as proof of timely mailing. (NOTE: These instructions replace the "Late Applications" instructions found in the PHS 5161-1.) If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day.

Applicants are advised that certain aspects of this program and one or more of the above receipt dates may be withdrawn, depending on the availability of funds. The SAMHSA Center for Substance Abuse Treatment will annually publish in the Federal Register a Notice of Funding Availability (NOFA) and a statement of the applicable receipt dates for this program. Applicants are strongly encouraged to verify receipt dates and terms of funding before preparing and submitting applications.

CONSEQUENCES OF LATE SUBMISSION

Applications received after the specified receipt dates are subject to assignment to the next review cycle or may be returned to the applicant without review.

APPLICATION REQUIREMENTS/COMPONENT CHECK LIST

All applicants must use the Public Health Service (PHS) Grant Application form 5161-1 (Rev. 5/96) and follow the requirements and guidelines for developing an application presented in Part I Programmatic Guidance and Part II General Policies and Procedures Applicable to all SAMHSA Applications

for Discretionary Grants and Cooperative Agreements.

The application should provide a comprehensive framework and description of all aspects of the proposed project. It should be written in a manner that is self-explanatory to reviewers unfamiliar with the prior related activities of the applicant. It should be succinct and well organized, should use section labels that match those provided in the table of contents for the Program Narrative that follows, and must contain all the information necessary for reviewers to understand the proposed project.

To ensure that sufficient information is included for the technical merit review of the application, the Programmatic Narrative section of application must address, but is not limited to, issues raised in the sections of this document entitled:

1. Program Description and Project Requirements
2. Guidelines and Review Criteria for Applicant

A **COMPLETE** application consists of the following components **IN THE ORDER SPECIFIED BELOW**. A description of each of these components can be found in Part II.

_____FACE PAGE FOR THE PHS 5161-1 (Standard Form 424 - See Appendix A in Part II for instructions.)

_____ABSTRACT (not to exceed 30 lines)

_____TABLE OF CONTENTS (include page numbers for each of the major sections of the Program Narrative, as well as for each appendix)

_____BUDGET FORM (Standard Form 424A - See Appendix B in Part II for instructions.)

_____PROGRAM NARRATIVE (The information requested for sections A-D of the Program Narrative is discussed in the subsections with the same titles in Section II - Program Description and Project Requirements and Section III - Guidelines and Review Criteria for Applicant. **Sections A-D may not exceed 25 single-spaced pages. Applications exceeding these page limits will not be accepted for review and will be returned to the applicant.**)

- _____A. Statement of the Issue
- _____B. Program Plan
- _____C. Design, Methodology, Data Collection, and Analyses
- _____D. Project Management: Implementation Plan, Organization, Staff, Equipment/Facilities, Budget, and Other Support

There are no page limits for the following sections E-H except as noted in G. Biographical Sketches/Job Descriptions. Sections E-H will not be counted toward the 25 page limitation for sections A-D.

- _____E. Literature Citations (This section must contain complete citations, including titles and all authors, for literature cited in the application.)
- _____F. Budget Justification/Existing Resources/Other Support

_____Sections B, C, and E of the Standard Form 424A must be filled out according the instructions in Part II, Appendix B.

_____A line item budget and specific justification in narrative form for the first project year's direct costs AND for each future year must be provided. For contractual costs, provide a similar yearly breakdown and justification for ALL costs (including overhead or indirect costs.

_____All other resources needed to accomplish the project for the life of the grant (e.g., staff, funds, equipment, office space) and evidence that the project will have access to these, either through the grant or, as appropriate, through other resources, must be specified.

Other Support "Other Support" refers to all current or pending support related to this application. Applicant organizations are reminded of the necessity to provide full and reliable information regarding "other support," i.e., all Federal and non-Federal active or pending support. Applicants should be cognizant that serious consequences could result if failure to provide complete and accurate

information is construed as misleading to the PHS and could, therefore, lead to delay in the processing of the application. In signing the face page of the application, the authorized representative of the applicant organization certifies that the application information is accurate and complete.

For your organization and key organizations that are collaborating with you in this proposed project, list all currently active support and any applications/proposals pending review or funding that relate to the project. If there are none, state "none." For all active and pending support listed, also provide the following information:

1. Source of support (including identifying number and title).
2. Dates of entire project period.
3. Annual direct costs supported/requested.
4. Brief description of the project.
5. Whether project overlaps, duplicates, or is being supplemented by the present application; delineate and justify the nature and extent of any programmatic and/or budgetary overlaps.

 G. Biographical Sketches/Job Descriptions

A biographical sketch must be included for the project director and for other key positions. Each of the biographical sketches must not exceed **2 pages** in length. In the event that a biographical sketch is included for an individual not yet hired, a letter of commitment from that person must be included with his/her biographical sketch. Job descriptions for key personnel must not exceed **1 page** in length. The suggested contents for biographical sketches and job descriptions are listed in Item 6 in the Program Narrative section of the PHS 5161-1.

 H. Confidentiality/Protection of Human Subjects

The information provided in this section will be used to determine whether the level of protection of human subjects appears adequate or whether further provisions are needed, according to standards set forth in Title 45, Part 46, of the Code of Federal Regulations. Adequate protection of human subjects is an essential part of an

application and will be considered in funding decisions.

Projects proposed under this announcement may expose participants to risks in as many ways as projects can differ from each other. Following are some examples, but they do not exhaust the possibilities. Applicants should report in this section any foreseeable risks for project participants, and the procedures developed to protect participants from those risks, as set forth below. Applicants should discuss how each element will be addressed, or why it does not apply to the project.

Note: So that the adequacy of plans to address protection of human subjects, confidentiality, and other ethical concerns can be evaluated, the information requested below, which may appear in other sections of the narrative, should be included in this section of the application as well.

1. Protection from Potential Risks:

(a) Identify and describe any foreseeable physical, medical, psychological, social, legal, or other risks or adverse effects, besides the confidentiality issues addressed below, which are due either to participation in the project itself, or to the evaluation activities.

(b) Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects and the rationale for their nonuse.

(c) Describe the procedures that will be followed to minimize or protect participants against potential risks, including risks to confidentiality.

(d) Where appropriate, specify plans to provide needed professional intervention in the event of adverse effects to participants.

2. Equitable selection of participants:

Target population(s):

Describe the socio-demographic characteristics of the target population(s) for the proposed project,

including age, gender, racial/ethnic composition, and other distinguishing characteristics (e.g., homeless youth, foster children, children of substance abusers, pregnant women, institutionalized individuals, or other special population groups).

Recruitment and Selection:

(a) Specify the criteria for inclusion or exclusion of participants and explain the rationale for these criteria.

(b) Explain the rationale for the use of special classes of subjects, such as pregnant women, children, institutionalized mentally disabled, prisoners, or others who are likely to be vulnerable.

(c) Summarize the recruitment and selection procedures, including the circumstances under which participation will be sought and who will seek it.

3. Absence of Coercion:

(a) Explain whether participation in the project is voluntary or mandatory. Identify any potentially coercive elements that may be present (e.g., court orders mandating individuals to participate in a particular intervention or treatment program).

(b) If participants are paid or awarded gifts for involvement, explain the remuneration process.

(c) Clarify how it will be explained to volunteer participants that their involvement in the study is not related to services and the remuneration will be given even if they do not complete the study.

4. Appropriate Data Collection:

(a) Identify from whom data will be collected (e.g., participants themselves, family members, teachers, others) and by what means or sources (e.g., school records, personal interviews, written questionnaires, psychological assessment instruments, observation).

(b) Identify the form of specimens (e.g., urine, blood), records, or data. Indicate whether the material or data will be obtained specifically for evaluative/research purposes or whether use will be made of existing specimens, records, or data. Also, where appropriate, describe the provisions for monitoring the data to ensure the safety of subjects.

(c) Provide, in Appendix No. 6, entitled "Data Collection Instruments/Interview Protocols," copies of all available data collection instruments and interview protocols that will be used or proposed to be used in the case of cooperative agreements.

5. Privacy and Confidentiality:

Specify the procedures that will be implemented to ensure privacy and confidentiality, including by whom and how data will be collected, procedures for administration of data collection instruments, where data will be stored, who will/will not have access to information, and how the identity of participants will be safeguarded (e.g., through the use of a coding system on data records; limiting access to records; storing identifiers separately from data).

Note: If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records in accordance with the provisions of Title 42 of the Code of Federal Regulations, Part 2 (42 CFR, Part 2).

6. Adequate Consent Procedures:

(a) Specify what information will be provided to

participants regarding the nature and purpose of their participation; the voluntary nature of their participation; their right to withdraw from the project at any time, without prejudice; anticipated use of data; procedures for maintaining confidentiality of the data; potential risks; and procedures that will be implemented to protect participants against these risks.

(b) Explain how consent will be appropriately secured for youth, elderly, low literacy and/or for those who English is not their first language.

medical, Note: If the project poses potential physical, psychological, legal, social, or other risks, awardees may be required to obtain written informed consent.

(c) Indicate whether it is planned to obtain informed consent from participants and/or their parents or legal guardians, and describe the method of documenting consent. For example: Are consent forms read to individuals? Are prospective participants questioned to ensure they understand the forms? Are they given copies of what they sign?

Copies of sample (blank) consent forms should be included in Appendix No. 7, entitled "Sample Consent Forms." If appropriate, provide English translations.

Note: In obtaining consent, no wording should be used that implies that the participant waives or appears to waive any legal rights, is not free to terminate involvement with the project, or releases the institution or its agents from liability for negligence.

(d) Indicate whether separate consents will be obtained for different stages or aspects of the project, and whether consent for the collection of evaluative data will be required for participation in the project itself. For example, will separate consent be obtained for the collection of evaluation data in addition to the consent obtained for participation in the intervention, treatment, or

services project itself? Will individuals not consenting to the collection of individually identifiable data for evaluative purposes be permitted to participate in the project?

7. Risk/Benefit Discussion:

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

____ APPENDICES (Only the appendices specified below may be included in the application. **These appendices must not be used to extend or replace any of the required sections of the Program Narrative.** The total number of pages in the appendices **CANNOT EXCEED 30 PAGES**, excluding all instruments.)

- ____ Appendix 1: Organizational Structure/Timeline/Staffing Patterns
- ____ Appendix 2: Non-Supplantation of Funds Letter
- ____ Appendix 3: Letters of Coordination/Support
- ____ Appendix 4: Copy of Letter(s) to SSA(s)
- ____ Appendix 5: Documentation Verifying Partnership/Collaboration/Infrastructure
- ____ Appendix 6: Data Collection Instruments/Interview Protocols
- ____ Appendix 7: Sample Consent Forms

____ ASSURANCES NON-CONSTRUCTION PROGRAMS (STANDARD FORM 424B)

____ CERTIFICATIONS

____ DISCLOSURE OF LOBBYING ACTIVITIES

____ CHECKLIST PAGE (See Appendix C in Part II for instructions)

TERMS AND CONDITIONS OF SUPPORT

For specific guidelines on terms and conditions of support, allowable items of expenditure and alterations and renovations, applicants must refer to the sections in Part II by the same names. (In addition, in accepting the award the

Grantee agrees to provide SAMHSA with GPRA Client Outcome (if applicable) and Evaluation Data.)

Reporting Requirements

For the SAMHSA policy and requirements related to reporting, applicants must refer to the Reporting Requirements section in Part II.

Lobbying Prohibitions

SAMHSA's policy on lobbying prohibitions is applicable to this program; therefore, applicants must refer to the section in Part II by the same name.

AWARD DECISION CRITERIA

Applications will be considered for funding on the basis of their overall technical merit as determined through the IRG and the CSAT National Advisory Council review process.

Other award criteria will include:

- # Availability of funds.
- # Overall program balance in terms of geography (including rural/urban areas), race/ethnicity of proposed project population, and project size.
- # Evidence of nonsupplantation of funds.
- # Presence of documentation verifying partnership and collaboration between community-based organizations and researchers and goals of infrastructure.

CONTACTS FOR ADDITIONAL INFORMATION

Questions concerning program issues may be directed to:

Thomas Edwards, Jr.
Branch Chief, Organization of Services Branch/Division of
Practice and Systems Development
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Rockwall II, Suite 740

5600 Fishers Lane
Rockville, MD 20857
(301)443-8453

Questions regarding grants management issues may be directed to:

Peggy Jones
Grants Management Officer
Division of Grants Management, OPS
Substance Abuse and Mental Health Services Administration
Rockwall II, 6th Floor
5600 Fishers Lane
Rockville, Maryland 20857
(301)443-9666

APPENDIX A. BIBLIOGRAPHY

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APPENDIX B. DEFINITIONS

To aid the applicant in understanding terms used in this PA, specific terms are defined herein.

Community

The aggregate of entities of interest for this program and/or for the proposed project. The community may be a general population, persons receiving or in need of services, or persons or other entities which deliver substance abuse treatment services. It could be one or more referral/service networks.

For example: All treatment services for a specific population of clients; specified substance abuse problems (methamphetamine, crack, chronic alcoholism, etc.); a particular sub-population (young children, seniors, "hard core" substance abusers (e.g., those with a history of treatment failures); all substance abuse and ancillary service providers serving a neighborhood or other specified locale or population; or a neighborhood or town.

Evaluation (Project)

Project evaluations conducted under this PA are two tiered. *Compliance evaluation* must examine and assess compliance of project activities and outcomes with the approaches and results proposed and anticipated in the application and explain any significant divergence. *Evaluation of goals, objectives, and outcomes* (a) addresses the degree to which the project answered the original questions and/or developed the approach(es)/ product(s) or result(s) intended, and (b) seeks to identify the reasons for achieving the goals and objectives, or not.

For example: Compliance evaluation of a project which was proposed with a timetable and specific tasks, neither of which could be adhered to in the "real world" of project implementation, would include a description of the deviations from the initial proposed plan and a discussion of the reasons for the deviations and their effects on the project results. In the same project, the deviations may have supported outcomes and achievements which were as good as those originally proposed, or even better; again, the discussion would include consideration of the quality of the results and outcomes.

New and Useful Knowledge

"Knowledge" in this context is information, understanding(s), techniques, and approaches which relate to substance abuse treatment, populations, services, systems, and environments. "New" means that the project, if successful, will result in some addition to existing knowledge and understanding, approaches, systems, and environments. "Useful" means that the "new knowledge" is delivered in one or more formats which can be useful to treatment providers, communities, systems, etc., whether the findings are positive or negative.

For example: A practical treatment service record system for tracking, accounting for, and reporting on multiple sources of funding; a counselor's work aid to assist in referring outlier clients; materials and procedures for providers of primary care and other non-substance abuse treatment services to identify, refer, support, and follow up on the abusers in their caseloads/practices.

Program/Project

The term "program" refers to the broad range of activities supported by, and immediately relating to, this announcement. A "project" is an activity supported by a single grant made pursuant to this program.

For example: Under the comprehensive community treatment "program," "projects" may address clinical, systemic, or environmental aspects of substance abuse treatment.

Special Population

Persons receiving, or in need of, substance abuse treatment services, who collectively have been found to be difficult to identify and/or treat satisfactorily, and/or for whom treatment has not generally been proven effective. Populations may be special due to the complexity and number of their problems, their inaccessibility from treatment providers (for geographic, socioeconomic, cultural, or financial reasons, etc.), and/or the difficulty experienced by treatment providers in their attempts to reach and address the population.

Treatment

Unless otherwise specified, the term "treatment" refers specifically and only to substance abuse treatment, and potentially includes all modalities and treatment environments and approaches.

For example: A "treatment provider" is specifically understood to be a provider of substance abuse treatment services. "Treatment services" are the substance abuse treatment activities undertaken by the provider.

APPENDIX C. CSAT'S GPRA STRATEGY¹

OVERVIEW

The Government Performance and Results Act of 1993 (Public Law-103-62) requires all federal departments and agencies to develop strategic plans that specify what they will accomplish over a three to five year period, to annually set performance targets related to their strategic plan, and to annually report the degree to which the targets set in the previous year were met. In addition, agencies are expected to regularly conduct evaluations of their programs and to use the results of those evaluations to "explain" their success and failures based on the performance monitoring data. While the language of the statute talks about separate Annual Performance Plans and Annual Performance Reports, OMB has chosen to incorporate the elements of the annual reports into the annual President's Budget and supporting documents. The following provides an overview of how the Center for Substance Abuse Treatment, in conjunction with the Office of the Administrator/SAMHSA, CMHS, and CSAP, are addressing these statutory requirements.

DEFINITIONS

Performance Monitoring involve	The ongoing measurement and reporting of program accomplishments, particularly progress towards preestablished goals. The monitoring can process, output, and outcome measures.
Evaluation	Individual systematic studies conducted periodically or "as needed" to assess how well a program is working and why particular outcomes have (or have not) been achieved.
Program	For GPRA reporting purposes, a set of activities that have a common purpose and for which targets

¹This document should be considered a "work-in-progress". Comments, questions, and suggestions are welcome and should be directed to Roger Straw, Deputy Director, OESAS/CSAT.

can (will) be established.²

Activity	A group of grants, cooperative agreements, and contracts that together are directed toward a common objective.
Project	An individual grant, cooperative agreement, or contract.

CENTER (OR MISSION) GPRA OUTCOMES

The mission of the Center for Substance Abuse Treatment is to support and improve the effectiveness and efficiency of substance abuse treatment services throughout the United States. However, it is not the only agency in the Federal government that has substance abuse treatment as part of its mission. The Health Care Financing Administration, Department of Veterans Affairs, and the Department of Justice all provide considerable support to substance abuse treatment. It shares with these agencies responsibility for achieving the objectives and targets for Goal 3 of the Office of National Drug Control Policy's Performance Measures of Effectiveness: Reduce the Health and Social Costs Associated with Drug Use.

Objective 1 is to support and promote effective, efficient, and accessible drug treatment, ensuring the development of a system that is responsive to emerging trends in drug abuse. The individual target areas under this objective include reducing the treatment gap (Goal 3.1.1), demonstrating improved effectiveness for those completing treatment (Goal 3.1.2), reducing waiting time for treatment (Goal 3.1.3), implementing a national treatment outcome monitoring system (Goal 3.1.4), and disseminating treatment information (Goal

²GPRA gives agencies broad discretion with respect to how its statutory programs are aggregated or disaggregated for GPRA reporting purposes. However, logic would seem to dictate that choosing categories that are easily understood by OMB and Congress (i.e., translate simply into authorized and/or appropriated programs) would be best. If the GPRA "programs" differ significantly, it is likely that, over time, Congress and OMB will seek to bring the two into alignment. As will become apparent below, SAMHSA has chosen to pursue "functional" program designations that are only loosely aligned with budget categories.

3.1.5). Objective 4 is to support and promote the education, training, and credentialing of professionals who work with substance abusers.

CSAT will be working closely with the OAS/SAMHSA, ONDCP, and other Federal demand reduction agencies to develop annual targets and to implement a data collection/information management strategy that will provide the necessary measures to report on an annual basis on progress toward the targets presented in the ONDCP plan. These performance measures will, at an aggregate level, provide a measure of the overall success of CSAT's activities. While it will be extremely difficult to attribute success or failure in meeting ONDCP's goals to individual programs or agencies, CSAT is committed to working with ONDCP on evaluations designed to attempt to disaggregate the effects. With regard to the data necessary to measure progress, the National Household Survey on Drug Abuse (conducted by SAMHSA) is the principal source of data on prevalence of drug abuse and on the treatment gap. Assessing progress on improving effectiveness for those completing treatment requires the implementation of a national treatment outcome monitoring system (Target 3.1.4). ONDCP is funding an effort to develop such a system and it is projected in Performance Measures of Effectiveness to be completed by FY 2002.

Until then, CSAT will rely on more limited data, generated within its own funded grant programs, to provide an indication of the impact that our efforts are having in these particular target areas. It will not be representative of the overall national treatment system, nor of all Federal activities that could affect these outcomes. For example, from its targeted capacity expansion program (funded at the end of FY 1998), CSAT will present baseline data on the numbers of individuals treated, percent completing treatment, percent not using illegal drugs, percent employed, and percent engaged in illegal activity (i.e., measures indicated in the ONDCP targets) in its FY 2001 report with targets for future years. As the efforts to incorporate outcome indicators into the SAPT Block Grant are completed over the next several years, these will be added to the outcomes reported from the targeted capacity expansion program.

In addition to these "end" outcomes, it is suggested that CSAT consider a routine customer service survey to provide the broadest possible range of customers (and potential customers)

with a means of providing feedback on our services and input into future efforts. We would propose an annual survey with a short, structured questionnaire that would also include an unstructured opportunity for respondents to provide additional input if they so choose.

CSATs "PROGRAMS" FOR GPRA REPORTING PURPOSES

All activities in SAMHSA (and, therefore, CSAT) have been divided into four broad areas or "programmatic goals" for GPRA reporting purposes:

- ! Goal 1: Bridge the gap between research and practice
- ! Goal 2: Promote the adoption of best practices
- ! Goal 3: Assure services availability/meet targeted needs
- ! Goal 4: Enhance service system performance³

The following table provides the crosswalk between the budget/statutory authorities and the "programs":

	KD&A	TCE	HRV	CH MH	SAPTBG	MHBG	P&A	PATH	NDC
Goal 1	X		X						
Goal 2	X								
Goal 3		X		X	X	X	X	X	
Goal 4					X	X			X

KD-Knowledge Development

KA-Knowledge Application

TCE-Targeted Capacity Expansion

HRV-High Risk Youth

CH MH-Children's Mental Health

SAPTBG-Substance Abuse Prevention and Treatment Block Grant

MHBG-Mental Health Block Grant

³Goal 4 activities are, essentially, those activities that are funded with Block Grant set-aside dollars for which SAMHSA seeks a distinction in the budget process (i.e., National Data Collection/Data Infrastructure).

P&A-Protection and Advocacy for Individuals with Mental Illness
PATH-Projects for Assistance in Transition from Homelessness
NDC-National Data Collection/Data Infrastructure

For each GPRA [program] goal, a standard set of output and outcome measures across all SAMHSA activities is to be developed that will provide the basis for establishing targets and reporting performance. While some preliminary discussions have been held, at this time there are no agreed upon performance measures or methods for collecting and analyzing the data.⁴ In the following sections, CSAT's performance monitoring plans for each of the programmatic areas are presented. It should be understood that they are subject to change as the OA and other Centers enter into discussion and negotiate final measures. In addition, at the end of the document, a preliminary plan for the use of evaluation in conjunction with performance monitoring is presented for discussion purposes.

BRIDGE THE GAP BETWEEN RESEARCH AND PRACTICE

This "program" or goal covers that set of activities that are knowledge development/research activities. Initially funded in FY 1996, CSAT's portfolio in this area currently includes XX multi-site grant and cooperative agreement programs, several of which are being conducted in collaboration with one or more of the other two Centers. These activities cover a broad range of substance abuse treatment issues including adult and adolescent treatment, treatments for marijuana and methamphetamine abuse, the impact of managed care on substance abuse treatment, and the persistence of treatment effects. In FY 1999, a general program announcement to support knowledge development activity will be added to the CSAT portfolio.

The purpose of conducting knowledge development activities within CSAT is to provide answers to policy-relevant questions or develop cost-effective approaches to organizing or

⁴Only measures of client outcomes have been developed and agreed to by each of the Centers. However, these measures are really only appropriate for "services" programs where the provision of treatment is the principal purpose of the activity (i.e., Goal 3). The client outcome measures will be presented under Goal 3. They are not appropriate as "outcomes" for the other three goals.

providing substance abuse treatment that can be used by the field. Simplistically then, there are two criteria of success for knowledge development activities:

- ! Knowledge was developed; and
- ! The knowledge is potentially useful to the field.

While progress toward these goals can be monitored during the conduct of the activity, only after the research data are collected, analyzed, and reported can judgments about success be made.

CSAT proposes to use a peer review process, conducted after a knowledge development activity has been completed, to generate data for GPRA reporting purposes. While the details remain to be worked out, the proposal would involve having someone (e.g., the Steering Committee in a multi-site study) prepare a document that describes the study, presents the results, and discusses their implications for substance abuse treatment. This document would be subjected to peer review (either a committee, as is done for grant application review or "field reviewers", as is done for journal articles). The reviewers would be asked to provide ratings of the activity on several scales designed to represent the quality and outcomes of the work conducted (to be developed).⁵ In addition, input on other topics (such as what additional work in the area may be needed, substantive and "KD process" lessons learned, suggestions for further dissemination) would be sought. The data would be aggregated across all activities completed (i.e., reviewed) during any given fiscal year and reported in the annual GPRA report.

PROMOTE THE ADOPTION OF BEST PRACTICES

This "program" involves promoting the adoption of best practices and is synonymous currently with Knowledge

⁵The ratings would include constructs such as adherence to PA requirements, use of reliable and valid methods, extent of dissemination activities, extent of generalizability, as well as the principal GPRA outcome constructs.

Application.⁶ Within CSAT, these activities currently include the Product Development and Targeted Dissemination contract (to include TIPS, TAPS, CSAT by Fax, and Substance Abuse in Brief), the Addiction Technology Transfer Centers, and the National Leadership Institute. In FY 1999, the Community Action Grant program will be added and in FY 2000, the Implementing Best Practices Grant program will be added.

Activities in this program have the purpose of moving "best practices", as determined by research and other knowledge development activities, into routine use in the treatment system. Again simplistically, the immediate success of these activities can be measured by the extent to which they result in the adoption of a "best practice."⁷ In order to provide appropriate GPRA measures in this area, CSAT plans to require that all activities that contribute to this goal to collect information on the numbers and types of services rendered, the receipt of the service by the clients and their satisfaction with the services, and whether the services resulted in the adoption of a best practice related to the service rendered.

ASSURE SERVICES AVAILABILITY/MEET TARGETED NEEDS

Into this program goal area fall the major services activities of CSAT: the Substance Abuse Prevention and Treatment Block Grant and the Targeted Capacity Expansion Grants. Simplistically, the following questions need to be answered about these activities within a performance monitoring context:

⁶Most, if not all, of the activities conducted under the rubric of technical assistance and infrastructure development are appropriately classified as activities supporting this program goal. Technical assistance activities within GPRA have not been discussed within CSAT. Further, at this time, SAMHSA has a separate program goal for infrastructure development (see "Enhance Service System Performance," below).

⁷Ultimately, the increased use of efficient and effective practices should increase the availability of services and effectiveness of the system in general. However, measures of treatment availability and effectiveness are not currently available. Within existing resources, it would not be feasible to consider developing a system of performance measurement for this purpose.

- ! Were identified needs met?
- ! Was service availability improved?
- ! Are client outcomes good (e.g., better than benchmarks)?

The client outcome assessment strategy mentioned earlier will provide the data necessary for CSAT to address these questions. The strategy, developed and shared by the three Centers, involves requiring each SAMHSA project that involves services to individuals to collect a uniform set of data elements from each individual at admission to services and 6 and 12 months after admission. The outcomes (as appropriate) that will be tracked using this data are:

- ! Percent of adults receiving services increased who:
 - a) were currently employed or engaged in productive activities;
 - b) had a permanent place to live in the community;
 - c) had reduced involvement with the criminal justice system;
 - d) had no past month use of illegal drugs or misuse of prescription drugs; and
 - e) experienced reduced alcohol or illegal drug related health, behavior, or social consequences, including the misuse of prescription drugs.
- ! Percent of children/adolescents under age 18 receiving services who:
 - a) were attending school;
 - b) were residing in a stable living environment;
 - c) had no involvement in the juvenile justice system;
 - d) had no past month use of alcohol or illegal drugs; and
 - e) experienced reduced substance abuse related health, behavior, or social consequences.

These data, combined with data taken from the initial grant applications, will enable CSAT to address each of the critical success questions.

ENHANCE SERVICE SYSTEM PERFORMANCE

As described earlier, this programmatic goal is distinguished from "Promote the adoption of best practices" primarily by its reliance on the Block Grant set-aside for funding and the

explicit emphasis on "systems" rather than more broadly on "services." The CSAT activities that fall into this goal are the STNAP and TOPPS. While CSAT has established performance measures for these activities individually, it is waiting for SAMHSA to take the lead in developing SAMHSA-wide measures. In addition, CSAT continues to believe that this goal should be collapsed into the broader goal of "Promoting the adoption of best practices."

EVALUATIONS

As defined earlier, evaluation refers to periodic efforts to validate performance monitoring data; to examine, in greater depth, the reasons why particular performance measures are changing (positively or negatively); and to address specific questions posed by program managers about their programs. These types of evaluation are explicitly described, and expected, within the GPRA framework. In fact, on an annual basis, the results of evaluations are to be presented and future evaluations described.

To date, CSAT has not developed any evaluations explicitly within the GPRA framework. The initial requirements will, of necessity, involve examinations of the reliability and validity of the performance measures developed in each of the four program areas. At the same time, it is expected that CSAT managers will begin to ask questions about the meaning of the performance monitoring data as they begin to come in and be analyzed and reported. This will provide the opportunity to design and conduct evaluations that are tied to "real" management questions and, therefore, of greater potential usefulness to CSAT. CSAT will be developing a GPRA support contract that permits CSAT to respond flexibly to these situations as they arise.

On a rotating basis, program evaluations will be conducted to validate the performance monitoring data and to extend our understanding of the impacts of the activities on the adoption of best practices.

